



Law
PATENT

Attorney's Docket No.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Berez, et al.

Application No.: 10/724,010 Group No.: 3733
Filed: November 25, 2003 Examiner: Philogene, P.
For: Patient Selectable Joint Arthroplasty Devices and Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Total and Partial Joint Arthroplasty

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT AFTER
MAILING DATE OF FINAL ACTION, NOTICE OF ALLOWANCE
OR ACTION THAT CLOSSES PROSECUTION BUT BEFORE
PAYMENT OF ISSUE FEE (37 C.F.R. § 1.97(d))**

**TIME OF TRANSMITTAL OF ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed *after* a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

☒ with sufficient postage as first class mail.

37 C.F.R. § 1.10*

☐ as "Express Mail Post Office to Addressee"
Mailing Label No. _____ (mandatory)

TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____ - _____

[Signature]
Signature

Date: February 27, 2007

Alexander J. Smolenski, Jr.

(type or print name of person certifying)

** Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

STATEMENT AND FEE

2. In accordance with the requirements of 37 C.F.R. § 1.97(d):
- A. Accompanying this transmittal is a statement, as specified in 37 C.F.R. § 1.97(e).
 - B. Applicant submits the fee set forth in § 1.17(p) (\$180.00).

FEE DUE

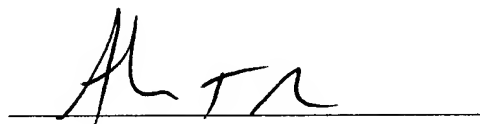
3. Fee due (§ 1.17(p)): \$180.00

METHOD OF PAYMENT OF FEE

4. Enclosed is a check in the amount of \$180.00

Charge any additional fees required by this paper or credit any overpayment to Deposit Account No. 19-4972.

Date: February 27, 2007



Alexander J. Smolenski, Jr.
BROMBERG & SUNSTEIN LLP
Customer Number 02101
125 Summer Street
Boston, MA 02110-1618
US

02960/00116 624832.1

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Berez, et al. Attorney Docket: 2960/116
 Serial No: 10/724,010 Art Group Unit: 3733
 Date Filed: November 25, 2003 Examiner Name: Philogene, P.
 Invention: **Patient Selectable Joint Arthroplasty Devices And Surgical Tools Facilitating Increased Accuracy, Speed And Simplicity In Performing Total And Partial Joint Arthroplasty**

**LIST OF PATENTS AND PUBLICATIONS FOR
 APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

OTHER DOCUMENTS		
Examiner Initials	Reference Number	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	BX	Radermacher, Klaus; Helmholtz Institute of Biomedical Technology, "Computer-Assisted Planning and Execution of Orthopedic Surgery Using Individual Surgical Templates", May 18, 1999
	BY	German version Radermacher, Klaus; Helmholtz Institute of Biomedical Technology, "Computer-Assisted Planning and Execution of Orthopedic Surgery Using Individual Surgical Templates", May 18, 1999
	BZ	Radermacher, Klaus, "Computer Assisted Orthopaedic Surgery With Image Based Individual Templates" <i>Clinical Orthopaedics</i> , Sept. 1998, Vol. 354, pp. 28-38
	CA	Portheine, F., Radermacher K., Zimolong, A., et al: "Development of a Clinical Demonstrator for Computer Assisted Orthopedic Surgery with CT Image Based Individual Templates." In Lemke HU, Vannier MW, Inamura K (eds). <i>Computer Assisted Radiology and Surgery</i> . Amsterdam, Elsevier 944-949, 1997
	CB	Radermacher, K., Protheine, F., Zimolong, A., et al: "Image Guided Orthopedic Surgery Using Individual Templates – Experimental Results and Aspects of the Development of a Demonstrator for Pelvis Surgery." In Troccaz J. Grimson E., Mosges R (eds). <i>Computer Vision, Virtual Reality and Robotics in Medicine and Medical Robotics and Computer Assisted Surgery, Lecture Notes in Computer Science</i> . Berlin, Springer-Verlag 606-616, 1997
	CC	Radermacher, K., Rau, G., Staudte HW: "Computer Integrated Orthopedic Surgery – Connection of Planning and Execution in Surgical Inventions." In Taylor, R., Lavallee, S., Burdea G. Mosges, R. (eds). <i>Computer Integrated Surgery</i> . Cambridge, MIT press 451-463, 1996
	CD	Radermacher, K., Staudte HW, Rau, G.: "Technique for Better Execution of CT Scan Planned Orthopedic Surgery on Bone Structures." In Lemke HW, Inamura, K., Jaffe, CC, Vannier, MW (eds). <i>Computer Assisted Radiology</i> , Berlin, Springer 933-938, 1995.

	CE	Radermacher, K., Staudte, HW, Rau, G.: "CT Image Based Planning and Execution of Interventions in Orthopedic Surgery Using Individual Templates – Experimental Results and Aspects of Clinical Applications." In Nolte LP, Ganz, R. (eds). <i>CAOS – Computer Assisted Orthopaedic Surgery</i> . Bern, Hans Huber (In Press) 1998.
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Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Berez, et al.
 Application No.: 10/724,010 Group No.: 3733
 Filed: November 25, 2003 Examiner: Philogene, P.
 For: PATIENT SELECTABLE JOINT ARTHROPLASTY DEVICES AND SURGICAL TOOLS
 FACILITATING INCREASED ACCURACY, SPEED AND SIMPLICITY IN PERFORMING
 TOTAL AND PARTIAL JOINT ARTHROPLASTY

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 P.O. Box 1450
 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

(Supplemental Information Disclosure Statement--Page 1 of 8)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*
 (When using Express Mail, the Express Mail label number is *mandatory*;
 Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"
 Mailing Label No. (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

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Date: February 27, 2007

Signature

Alexander J. Smolenski, Jr.

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).
 "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Supplemental Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ International Search Report
 - 7B. ☐ English Language Version of International Search Report
8. ☒ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Supplemental Information Disclosure Statement

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary Statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this supplemental information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this supplemental information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

U.S. patent citations are not included pursuant to the United States Patent and Trademark Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

Section 8. Translation(s) of Non-English Language Documents

NOTE: "If a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in section 1.56(c), a copy of the translation shall accompany the statement." 37 C.F.R. section 1.98(c).

NOTE: "The Office does not intend to require translations unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. Applicants should note, however, that most examiners do not have the ability to understand information which is not in English and that the Office will not routinely translate information submitted in a non-English language. The examiner will consider the information insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, but will not have the information translated unless it appears to be necessary to do so. Applicants are required to aid the examiner by complying with the requirements for a concise explanation in section 1.98(a)(3) for information submitted in a non-English language." Notice of January 9, 1992, 1135 O.G. 13-25, at 21.

NOTE: "The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English." Notice of April 20, 1992 (1138 O.G. 37-41, 41).

- [x] Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material: **Reference BX**

(complete the following, if applicable)

- [] No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.
- [] The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

Section 10. Identification of Person(s) Making This Supplemental Information Disclosure Statement

The person making this certification is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

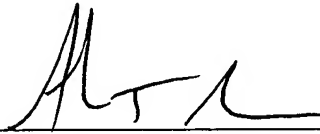
(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.



SIGNATURE OF PRACTITIONER

Alexander J. Smolenski, Jr.
(type or print name of practitioner)

125 Summer Street, 11th Floor
P.O. Address

Boston, MA 02110-1618

Reg. No.: 47,953

Tel. No.: (617) 443-9292

Customer No.: 002101

02960/00116 624568.1



Practitioner's Docket No.: 2960/116

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Berez, et al
Application No.: 10/724,010
Filed: November 25, 2003
For: **PATIENT SELECTABLE JOINT ARTHROPLASTY DEVICES AND SURGICAL TOOLS
FACILITATING INCREASED ACCURACY, SPEED AND SIMPLICITY IN PERFORMING
TOTAL AND PARTIAL JOINT ARTHROPLASTY**

Group No.: 3733
Examiner: Philogene, P.

**Attn: Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

STATEMENT FOR INFORMATION DISCLOSURE UNDER 37 C.F.R. SECTION 1.97(e)

NOTE: A statement must state either: "(1) that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement." 37 C.F.R. Section 1.97(e).

NOTE: "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

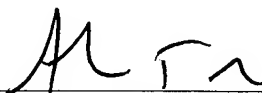
MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office, (703) ____-____.

Date: February 27, 2007



Alexander J. Smolenski, Jr.
(type or print name of person certifying)

a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a communication from a foreign patent office in a counterpart foreign application, the certification can be properly made regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19.

NOTE: "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus, for example, the certification of Section 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications, even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

NOTE: A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: "The phrase 'after making reasonable inquiry' makes it clear that the individual making the certification has a duty to make reasonable inquiry regarding the facts that are being certified. The certification can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a certification under 37 C.F.R. 1.97(e)(2) to the Office until a satisfactory response is received. The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under Section 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

NOTE: The mere absence of an item of information for a foreign patent office communication is not intended to represent an opportunity to delay the submission of a item known more than three months prior to the filing of an information disclosure statement to an individual having the duty of disclosure under Section 1.56. 62 Fed. Reg. 53,131, 53,150 (Oct. 10, 1997).

NOTE: "The certification under Section 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 9, 1992, 1135 O.G. 13-25 at 19.

NOTE: "The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 C.F.R. Section 1.56(d) and

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) each inventor named in the application;

(2) each attorney or agent who prepares or prosecutes the application; and

(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. Section 1.56(c).

**IDENTIFICATION OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
FOR WHICH THIS STATEMENT IS BEING MADE**

1. This statement is being made for the Supplemental Information Disclosure Statement
[x] accompanying this statement.
[] filed _____
Date

STATEMENT

2. I, the person(s) signing below state:

[] that each item of information contained in the supplemental information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the supplemental information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

NOTE: The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 19. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

OR

[x] that no item of information contained in the supplemental information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three (3) months prior to the filing of the supplemental information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

NOTE: "The time at which information 'was known to any individual designated in 37 C.F.R. 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

IDENTIFICATION OF PERSON(S) MAKING THIS STATEMENT

3. The person making this statement is

(check each applicable item)

(a) [] the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) [] a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an

obligation to assign the application (37 C.F.R. Section 1.56(c)) and who signs below.

SIGNATURE OF PERSON MAKING STATEMENT

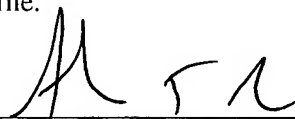
(type name of person who is signing)

Address of person who is signing

(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
☐ supplied by an individual designated in Section 1.56(c).
☒ in the practitioner's file.



SIGNATURE OF PRACTITIONER

Alexander J. Smolenski, Jr.

(type or print name of practitioner)

Reg. No.: 47,953

Tel. No. (617) 443-9292

125 Summer Street

P.O. Address

Customer No.: 002101

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